RIBOXIN®

INTERNATIONAL NON-PROPRIETARY NAME (INN): Inosine.
DOSAGE FORM AND STRUCTURE:
Composition (tablets):
Active ingredient: inosine (Riboxin) - 200 mg in terms of 100% substance.
Excipients (core): microcrystalline cellulose - 40.0 mg, sucrose - 40.0 mg, potato starch - 17.0 mg, povidone (polyvinylpyrrolidone) - 10.0 mg, croscarmellose sodium - 6.0 mg, magnesium stearate - 3.0 mg, purified water - 4.0 mg.
Excipients (coating): hypromellose - 5.5 mg, polysorbate-80 - 1.5 mg, titanium dioxide - 3.0 mg.

Composition (ampules):

Active ingredient: inosine (Riboxin) - 20 mg.
Excipients: methenamine (hexamethylenetetramine) - 2 mg, 1M sodium hydroxide solution - up to pH 7.8-8.6, water for injection - up to 1 ml.

DESCRIPTION:
Riboxin® tablets: film-coated tablets of a biconvex form without a break-line. Color ranges from white to pale orange. Slight surface roughness is allowed.
Riboxin® ampules: clear, colourless or slightly tinted liquid.

ATC CODE: C01EB Other cardiac preparations.

PHARMACOLOGICAL ACTION: metabolic agent.

PHARMACODYNAMICS:
Inosine is a metabolic agent, a precursor of adenosine triphosphate (ATP). It provides antihypoxic, metabolic and antiarrhythmic effect. It increases the energy balance of the myocardium, improves the coronary blood flow and prevents consequences of intraoperative renal ischemia. The drug participates in the glucose metabolism and promotes metabolism activation under hypoxia and in the absence of ATP.
It activates the metabolism of pyroracemic acid required for the normal functioning of the tissue respiration, and also promotes activation of xanthine dehydrogenase. It stimulates the synthesis of nucleotides and enhances the activity of certain enzymes of the Krebs cycle. Entering the cells, it provides positive effect on metabolic processes in the myocardium: increases the power of heart beats and facilitates a deeper relaxation of myocardium in the diastole, as a result the stroke volume increases.
It reduces thrombocytes aggregation and activates tissues regeneration (especially of the myocardium and the mucous membrane of the gastrointestinal tract).

PHARMACOKINETICS:
Riboxin is metabolized in the liver with the formation of glucuronic acid and its subsequent oxidation. It is excreted in a small amount by the kidneys.

INTENDED USES:
Riboxin is prescribed for adults in the complex treatment of coronary heart disease, myocardial dystrophy, after a myocardial infarction and heart rhythm disturbances caused by the use of cardiac glycosides. It is prescribed in case of hepatitis, cirrhosis, fatty degeneration of the liver

caused by alcohol or drugs, and urocoproporphyria. Riboxin® ampules are also prescribed in case of operations on an isolated kidney (as a means of pharmacological protection during blood circulation arrest).

CONTRAINDICATIONS:

Hypersensitivity to the drug, podagra, hyperuricemia; pregnancy, breastfeeding, children under 18 years old (efficiency and safety are not determined). Use with caution in renal failure.

DOSAGE AND ADMINISTRATION:

Riboxin® tablets:

Per os before meals. The maximum daily dose of the drug is 0.6 - 2.4 g. In the first days of treatment, the daily dose is 0.6 - 0.8 g (0.2 g 3-4 times a day). In case of good tolerability of the drug, during the next 2 - 3 days the dose is increased up to 1.2 g (0.4 g 3 times a day), if necessary - up to 2.4 g per day. The duration of the course is from 4 weeks to 1.5 - 3 months.
In urocoproporphyria, the daily dose is 0.8 g (0.2 g 4 times a day). The drug is taken daily for 1 to 3 months.

Riboxin®ampules:

The drug is used intravenously slowly, by stream or by drop infusion (40-60 drops per 1 minute). The treatment is commenced with an administration of 200 mg (10 ml of 20 mg / ml solution) once a day, then, in case of good tolerability, the dose is increased to 400 mg (20 ml of 20 mg / ml solution) 1 -2 times a day. The duration of treatment is 10-15 days.
The stream infusion of the drug is possible in case of acute cardiac rhythm disturbance in a single dose of 200-400 mg (10-20 ml of 20 mg / ml).
For pharmacological protection of ischemic kidneys, Riboxin is injected intravenously by stream infusion in a single dose of 1,200 mg (60 ml of 20 mg / ml solution) 5-15 minutes before clamping of the renal artery, and then 800 mg more (40 ml of 20 mg / ml solution) immediately after the restoration of the blood flow.
For intravenous injection by drop infusion, 20 mg / ml solution is diluted in 5% dextrose (glucose) solution or 0.9% sodium chloride solution (up to 250 ml).

SIDE EFFECTS:

Allergic reactions: urticaria, skin itching, dermahemia (the drug should be discontinued).
When taking the drug, there can rarely be an increase in the concentration of uric acid in the blood and exacerbation of gout (in case of a prolonged use in high doses).

OVERDOSE:

There have been no cases of the drug overdose in clinical practice.

INTERACTION WITH OTHER DRUGS:

- Concomitant use of immunosuppressants (including anti-thymocyte immunoglobulin, gamma-D-glutamyl-D-tryptophan, cyclosporine) reduces the effectiveness of inosine.
- In case of simultaneous use of the drug with cardiac glycosides, it can prevent the occurrence of arrhythmias, and enhance the positive inotropic effect.
- Steroid and non-steroid drugs: in combination with inosine, their anabolism increases.
- Theophylline and caffeine: when combined with Riboxin, they reduce relaxation of the smooth muscles of the bronchi and the stimulating effect of coffee is weakened.
- Vitamin B6: together, the components become ineffective.
- Alkaloids: inosine injections are not combined with alkaloids. Their combination will provide an insoluble substance.
- When combined with Heparin, the effect of the latter increases, and its duration is prolonged.

- Riboxin is recommended for use with Nitroglycerin, Furosemide, Nifedipine and Spironolactone.

PRECAUTION:
Riboxin is not used for emergency correction of cardiac abnormalities.
In case of renal failure, the use of the drug is possible only if, according to the doctor, the expected positive effect prevails over the possible risk to the patient.
During a prolonged treatment, it is advisable to control the concentration of uric acid in the blood and urine.

PREGNANCY AND LACTATION:
The use of Riboxin during pregnancy and breastfeeding is not recommended. There are no data on the use of the drug during pregnancy. The drug should be prescribed only in cases when the benefit to the mother outweighs the potential risk to the fetus.

INFLUENCE ON THE ABILITY TO DRIVE VEHICLES AND OPERATE MECHANISMS:
The drug does not adversely affect the performance of potentially hazardous activities that require an increased concentration of attention and speed of psychomotor reactions, as well as on driving vehicles.

STORAGE CONDITIONS:
Keep in a dry, dark place at a temperature not exceeding 25 ° C (77 ° F). Keep out of the reach of children.

SHELF LIFE:
3 years. Do not use beyond the expiration date.

MANUFACTURER:
PJSC Biosintez, http://biosintez.com/en/
OZON Pharmaceutical Company, https://ozonpharm.ru/en/